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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/691,915	10/23/2003	Anil Gulati	27611/38802A	6526

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MARSHALL, GERSTEIN & BORUN LLP  
6300 SEARS TOWER  
233 S. WACKER DRIVE  
CHICAGO, IL 60606

EXAMINER
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FETTEROLF, BRANDON J

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 03/08/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

*Office Action Summary*

Application No.

10/691,915

Applicant(s)

GULATI, ANIL

Examiner

Brandon J. Fetterolf, PhD

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-43 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-43 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_.

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Gulati, Anil

Pending Claims: 1-43

## DETAILED ACTION

### *Election/Restrictions*

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-13, as specifically drawn to a method of treating a solid tumor comprising administering a therapeutically effective amount of an endothelin B agonist and a therapeutically effective amount of a second agent, classified in class 514, subclass 12.  
(Upon election of Group I, the applicant must choose **ONE** endothelin agonist from Claim 4, as each endothelin agonist is a distinct invention requiring separate searches, NOT a species)
- II. Claims 14 and 16-17, as specifically drawn to a composition and an article of manufacture comprising a chemotherapeutic agent, and endothelin B agonist, and an optional excipient., classified in class 530, subclass 321.
- III. Claim 15, as specifically drawn to an article of manufacture comprising: (a) a packaged composition comprising an endothelin B agonist; (b) an insert providing instruction for administration of (a) to treat a solid tumor in a mammal; and (c) a container for (a) and (b), classified in class 530, subclass 321.
- IV. Claims 18-39, as specifically drawn to a method of treating a solid tumor comprising administering a therapeutically effective amount of an endothelin B antagonist, classified in class 514, subclass 408.  
(Upon election of Group IV, the applicant must choose **ONE** endothelin antagonist from Claims 23-27, as each endothelin antagonist is a distinct invention requiring separate searches, NOT a species)

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- V. Claims 40-42, as specifically drawn to a composition and an article of manufacture comprising an endothelin B antagonist and an angiogenesis inhibitor, classified in class 548, subclass 100.
- VI. Claim 43, as specifically drawn to an article of manufacture comprising: (a) a packaged composition comprising an endothelin B agonist; (b) an insert providing instruction for administration of (a) to treat a solid tumor in a mammal; and (c) a container for (a) and (b), classified in class 548, subclass 100.

The inventions are distinct, each from the other because of the following reasons:

The inventions of Groups I and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the specification does not disclose that these methods would be used together. The method for treating a solid tumor comprising administering an endothelin B agonist (Group I) and the method of treating a solid tumor comprising administering an endothelin B antagonist (Group IV) are unrelated as they comprise distinct steps and utilize different products which demonstrates that each method has a different mode of operation. Each invention performs this function using structurally and functionally divergent material. Moreover, the methodology and materials necessary for treatment differ significantly for each of the materials. For example, a solid tumor can be treated by administering an agonist along with a chemotherapeutic reagent or a solid tumor can be treated by administering an antagonist along with an anti-angiogenic inhibitor. Therefore, each method is divergent in materials, function of the agent being administered and steps. For these reasons the inventions of Groups I and IV are patentably distinct.

Furthermore, the distinct steps and products require separate and distinct searches of the literature. The inventions of Groups I and IV have a separate status in the art as shown by their different classifications. As such, it would be burdensome to search the inventions of Groups I and IV.

The inventions of Groups II-III and V-VI are related by the fact that each can be used in a method of treating a solid tumor. However, the composition and article of manufacture comprising an endothelin B agonist and a chemotherapeutic reagent (Group II), the article of manufacture comprising an endothelin B agonist alone (Group III), the composition and article of manufacture comprising an endothelin B antagonist and an angiogenesis inhibitor (Group V) and the article of manufacture comprising an endothelin B antagonist alone (Group V) represent separate and distinct products which are made by materially different methods each of which performs this function using structurally and functionally divergent material. Moreover, the methodology and materials necessary for carrying out the treatment differ significantly for each of the materials. For example, either an endothelin B agonist alone or a combination of an endothelin B agonist and a chemotherapeutic agent can be used to treat a solid tumor. This would than imply that the endothelin B agonist alone can be effective as treating a solid tumor alone, whereas for the combination therapy the endothelin B agonist may not be effective enough for treatment and requires the use of a chemotherapeutic reagent. Therefore, each product is divergent in materials and function. For these reasons the inventions of Groups II-III and V-VI are patentably distinct.

Furthermore, the distinct steps and products require separate and distinct searches of the literature. As such, it would be burdensome to search the inventions of Groups II-III and V-VI.

The inventions of Groups II-III and the method of Group I are related as products and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the method of treating a solid tumor can be practiced with another materially different product such as using a combination of an endothelin B agonist and a chemotherapeutic agent or an endothelin B agonist alone.

The inventions of Groups V-VI and the method of Group IV are related as products and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using

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that product (MPEP § 806.05(h)). In the instant case the method of treating a solid tumor can be practiced with another materially different product such as using a combination of an endothelin B antagonist and a angiogenesis inhibitor or an endothelin B antagonist alone.

Because the inventions are distinct for the reasons given above, have acquired a separate status in the art as shown by their different classification, and the search required for each group is not required for other groups because each group requires a different non-patent literature search due to each group comprising different products and/or method steps, restriction for examination purposes as indicated is proper.

### ***Species Election***

This application contains claims directed to the following patentably distinct species of the claimed invention. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Claims 2 and 19, Group I and IV, are generic to a plurality of disclosed patentably distinct species comprising the following tumors: ovarian tumor, colon tumor, Kaposi's sarcoma, breast tumor, a melanoma, prostate tumor, meningioma, liver tumor, and a breast phyllode tumor which differ at least in morphology and function such that one species could not be interchanged with the other. As such, each species would require different searches and the consideration of different patentability issues

Claim 6, Group I, is generic to a plurality of disclosed patentably distinct species comprising the following chemotherapeutic agents: adriamycin, camptothecin, carboplatin, ... topotecan which differ at least in chemical structure and mechanism of action such that one species could not be interchanged with the other. As such, each species would require different searches and the considerations of different patentability issues.

Claim 30, Group IV, is generic to a plurality of disclosed patentably distinct species comprising the following angiogenesis inhibitors: thalidomide, marimastat, COL-3, ... herceptin which differ at least in chemical structure and mechanism of action such that one species could not be interchanged with the other.

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Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Note:

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04.

**Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above

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policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brandon J Fetterolf, PhD whose telephone number is (571)-272-2919. The examiner can normally be reached on Monday through Friday from 8:30 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeff Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Brandon J Fetterolf, PhD  
Examiner  
Art Unit 1642

BF

  
**GARY NICKOL**  
**PRIMARY EXAMINER**